

Description	
Job Title	Mechanical Developer
Reports to Title	Senior Director of Engineering
General Accountability	<p>Our mission is to Profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate tissue with precision; a tomorrow where patients have access to safe and effective treatment options, so they can quickly return to their daily lives. Changing the standard of care is part of our fabric. We are a group of energetic, problem-solvers focused on innovation, and looking to change the world. If you want to make a Profound impact with your career, here is your chance.</p> <p>The Mechanical Developer is responsible for producing designs, test specifications and documentation of the mechanical and electro-mechanical designs, following the Company’s Quality System. They are responsible for resolving all mechanical issues and ensure that the design meet component and system specifications. They are involved in all aspects of the design process from requirements to transfer to manufacturing.</p> <p>The Mechanical Developer is expected to provide technical leadership with many aspect of the overall design of the Company’s products. This includes reviewing their peers’ design and those already developed by the Company and suggesting improvements to them.</p>
Duties and Responsibilities	<p>Duties and responsibilities will include (but are not limited to):</p> <ol style="list-style-type: none"> 1. Analyze user needs and generate requirements for the company’s products 2. Create design specifications for the mechanical aspects of the company’s products 3. Create aesthetic, functional, and reliable product designs 4. Review existing product design, identify weaknesses and propose improvements 5. Analyze mechanical designs 6. Build early concepts of new designs and prototypes 7. Create strategy for the verification of the design, and participate in verification activities as required 8. Produce DHF and DMR documentation for transfer to test/manufacturing 9. Participate in sourcing parts and qualifying suppliers 10. Support in-house production as needed 11. Interact with customers, marketing, and sales as required to capture user needs and look for opportunities to improve products 12. Investigate product complaints at clinical/customer sites, perform root cause analysis of failures, and propose remediation in a timely fashion 13. Develop clinical workflow, author content for the user manual, incorporate human factors into designs and train other employees

	<p>on product use</p> <ol style="list-style-type: none"> 14. Contribute to risk management content such as FMEA, PFMEA and hazard analysis 15. Perform all duties in compliance with the quality management system; actively contribute to the continuous improvement of the QMS 16. Perform project engineering roles as needed
Competencies	
Education	Mechanical Engineering or similar undergraduate degree
Certifications	None
Key Attributes (experience, skills and technical knowledge)	<p>Required:</p> <ul style="list-style-type: none"> ▪ 5+ years industrial experience preferably in medical device industry. ▪ Extensive knowledge of SolidWorks ▪ Knowledge of electro-mechanical design ▪ Excellent drafter ▪ Excellent verbal and written skills. Ability to quickly, clearly, and concisely communicate. ▪ Mechanical aptitude including ability to use common shop tools and measurement equipment ▪ Tenacious problem solver, organized, detail oriented ▪ Knowledge of medical device standards such as IEC-60601-1, ISO 10993 ▪ In depth knowledge of manufacturing processes such as machining, injection molding, urethane casting, 3D printing and sheet metal ▪ Demonstrated ability to translate user needs into design specifications ▪ Demonstrated ability to troubleshoot problems and perform root cause analysis ▪ Demonstrated ability to communicate with customers and with all employees of the company. ▪ Knowledge of ASTM standards and testing methods ▪ Competency in mechanical analysis skills such as kinematics, solid and fluid dynamics, heat transfer, material strength <p>Desired:</p> <ul style="list-style-type: none"> ▪ Experience working with MR compatible devices and therapeutic ultrasound devices. ▪ Familiar with mechatronics components sizing and sourcing ▪ Experience working with adhesives ▪ Knowledge of finite-element analysis ▪ Working knowledge of industrial design ▪ Experience working with sterilization and disinfection methods ▪ Experience with statistical analysis ▪ Experience using and designing with off-the-shelf medical components